

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of  
KELLY R. BROWN, ET AL.

U.S. Serial No.: 09/892,993

Confirmation No.: 3764

Filed: June 27, 2001

For: POROUS CERAMIC/POROUS  
POLYMER LAYERED SCAFFOLDS  
FOR THE REPAIR AND  
REGENERATION OF TISSUE

Group Art Unit: 1618

Examiner: Blessing M. Fubara

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**DECLARATION OF MR. YUFU LI UNDER 37 C.F.R. § 1.132**

I, Mr. Yufu Li, do hereby declare and say as follows:

1. I am a co-inventor of the above-referenced patent application.
2. I understand that the Examiner has rejected Claims 26-28 and 33-44 under 35 U.S.C. 103(a) as being unpatentable over Niederauer et al. "Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in Biomaterials, Vol. 21, Issue 24, pp. 2561-2574, 15 Dec. 2000. I also understand that Claims 26-44 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Niederauer et al. reference in view of Vyakarnam et al. U.S. Patent No. 6,306,424. I have reviewed the

Niederauer et al. reference in detail and conclude that it does not render the present invention obvious.

4. I have prepared a front view and three sectional views of the present invention in the drawings labeled "Our Structures" and "Cross section of our structure" (see attached Exhibit). The front view of the present invention shows a "100% Porous Pure Ceramic Layer," a "100% Porous Pure Polymer Layer," and an "Interpenetrated Porous Ceramic/ Porous Polymer interface." The sectional view labeled "100% Porous Pure Ceramic Layer" is taken along the horizontal axis at an area above the interface region, the sectional view labeled "Porous Ceramic/ Porous Polymer interface" is taken along the horizontal axis at the interface region, and the sectional view labeled "100% Porous Pure Polymer Layer" is taken along the horizontal axis at an area below the interface region.

5. Turning now to the scaffold disclosed in the Niederauer et al. reference, the ceramic and the polymer are blended with each other (see the Niederauer et al. reference, third and fourth paragraphs on the left column of page 2563) and the phases glued together (see the Niederauer et al. reference, sixth paragraph on the left column of page 2563).


6. I have drawn three sectional views of the scaffold disclosed in the Niederauer et al. reference (see the drawing labeled "Prior art Structures"). The sectional views are taken along the horizontal axis at three different portions of the scaffold (i.e., a top portion, a central portion, and a bottom portion). Each of these layers includes both ceramic and polymer.

7. The scaffold of the present invention includes at least two discrete layers and an interface attaching the layers to each other. One discrete layer includes only ceramic, while the other discrete layer includes only polymer.

8. In direct contrast, each layer of the scaffold disclosed in the Niederauer et al. reference is essentially a composite, which is bi-phasic (includes both ceramic and polymer).

9. I, the undersigned, declare further that all statements made herein are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 06/13/08

  
Mr. Yufu Li